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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,624	12/08/2000	David G. Lamphere	1611/122	2412

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EXAMINER

SORKIN, DAVID L

ART UNIT PAPER NUMBER

1723

17

DATE MAILED: 06/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,624

Applicant(s)

LAMPHERE ET AL.

Examiner

David L. Sorkin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 May 2003 has been entered.

Drawings

2. The corrected drawings received on 22 May 2003 are approved.

Claim Objections

3. Claim 6 is objected to because of the following informalities: In line 4 of the claim, the word "and" (first occurrence) should be deleted, so that "the chamber and defined by" reads - - the chamber define by - - .

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 has been amended to read "... according to claim, wherein...", making it unclear whether the claim is independent or dependent, and if dependent from which claim(s) it depends. Applicant states in applicant's

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remarks that claim 4 has been amended to depend from claim 1, but the amendment only deletes the number "3" and does not insert the number - 1 - .

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Headley et al. (US 5,885,239). Note: it has been assumed for the purposes of consideration with regard to the prior art that claim 4 depends from claim 1. See the rejection under section 112, second paragraph above. Regard claim 1, Headley ('239) discloses a fluid processing disposable set (see col. 7, lines 56-57, "disposable processing set") comprising a fluid port (83); a variable-volume chamber in fluid communication with the fluid port, the chamber defined by a rigid wall (10) (see col. 7, lines 41-43, "rigid boundary wall") and an elastic wall (31) (see col. 7, lines 37-40, "diaphragm 31 is preferably made of an elastic, stretchable and resilient material"); and a perforate interior wall (the portion of plate 40 which has holes) located within the chamber; the elastic wall formed by a convoluted diaphragm (31) (see Fig. 12; note that applicant admits on page 6 of paper No. 16 that Fig. 12 of the reference discloses a convoluted diaphragm), the elastic wall substantially adjacent the perforate interior wall in an unstretched state (See Figs. 11-13; col. 16, lines 34-55). Regarding claim 2, the set of Headley ('239) further comprises a rotary seal (48), the rotary seal coupled to the

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chamber (see Fig. 11). Regarding claim 4, the convoluted diaphragm has at least one fold (see Fig. 12 and applicant's admission on page 6 of paper No. 16 regarding Fig. 12). Regarding claim 5, the convoluted shaped diaphragm (31) has a plurality of folds (at least one on the outer periphery and at least one nearer the center which is discussed by applicant on page 6 of paper No. 16) the folds located symmetrically about an axis (see Fig. 12).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Headley et al. (US 5,885,239) in view of Lord et al. (US 1,885,457). Headley ('253) discloses a fluid processing disposable set (see col. 7, lines 56-57, "disposable

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processing set") comprising a fluid port (13/83) and a variable volume chamber in communication with the fluid port, the chamber defined by a rigid wall (10) (see col. 7, lines 41-43, "rigid boundary wall 10") and an elastic wall formed by a diaphragm (31) (see col. 7, lines 37-40, "diaphragm 31 is preferably made of an elastic, stretchable and resilient material"), the elastic wall sealed at a mounting position on the rigid wall (see col. 7, lines 35-38, "sealed to a rigid, imperforate boundary wall 10 by an O-ring or other means"); a rotary seal (48) coupled to the fluid port (see Fig. 2), the rotary seal fluidly coupled to the chamber, wherein the diaphragm is essentially planar in an unstretched position (see Figs. 2-4). Headley ('253) fails to disclose the diaphragm being "shaped" such that it has varying in thickness outside the immediate vicinity of the mounting position. Lord ('457) teaches a diaphragm (7) which is "shaped" such that it has varying in thickness outside the immediate vicinity of the mounting position (as required by instant claim 6) and the thickness is constant at locations equidistant from an axis (as required by instant claim 7) (see Figs. 1 and 2, page 1, lines 47-52; page 2, lines 3-29 and 41-57). It is considered that it would have been obvious to one of ordinary skill in the art to have varied the thickness of the diaphragm of Headley ('253) in the manner taught by Lord ('457), because Lord ('457) explains that such a varying of thickness provides the benefit of "surer union" between the diaphragm and other parts, while still allowing flexibility where needed (see page 1, lines 47-42).

Response to Arguments

11. Applicant's arguments have been considered but are moot in view of the new grounds of rejection. Asmussen (US 2,179,807) is not related upon to reject the

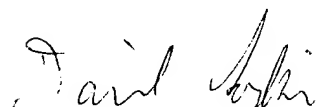
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amended claims, because, as applicant points out, a perforate wall located within the chamber is not disclosed. While Headley (US 5,885,239) only discloses varying thickness in the immediate vicinity of the mounting position, it is considered that it would have been obvious to one of ordinary skill in the art to have varied the thickness in other regions, in view of the teachings of Lord et al. (US 1,885,457) as discussed above regarding section 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 703-308-1121. The examiner can normally be reached on 8:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



David Sorkin

June 4, 2003